DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

94356d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-46

September 30, 2003

Lillie Metcalf, President
Alex Seafood Company
7710 Palmo Fish Camp Road
St. Augustine, Florida 32092

Dear Ms. Metcalf:

On August 18-20, 2003, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (cGMP) (21 CFR 110). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, cooked ready-to-eat crabmeat products (including lump, jumbo lump, claw, and cocktail claw fingers) are adulterated in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, Seafood HACCP Regulations, and cGMP Regulations through links in FDA's homepage at http:// www.fda.gov.

The deviations, observed during the inspection and upon further examination of the documents collected during that inspection, are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for fresh, cooked ready-to-eat crabmeat products (including lump, jumbo lump, claw, and cocktail claw fingers) to control the food safety hazards of pathogen growth/toxin formation through time/temperature abuse and pathogen survival through cooking. When our investigator asked to see your HACCP plan, you informed her that you had thrown it out because your family cat had delivered kittens on the document and had ruined it. This same violation was brought to your attention in our letter to you dated June 15, 1999.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for all eight areas of sanitation required for the processing of fresh, cooked ready-to-eat crabmeat products for various processing days for the year 2003. Cooking log records collected by our investigator for May 27, 2003, August 15, 2003, and August 17, 2003, indicate that your firm was processing on these days. However, no accompanying sanitation records were available for these dates. Additionally, a sanitation record log collected by our investigator for August 19, 2003, shows missing entries for the 2 pm checks on that day. Your failure to maintain sanitation records by your firm was also discussed in our letter to you dated June 15, 2003.

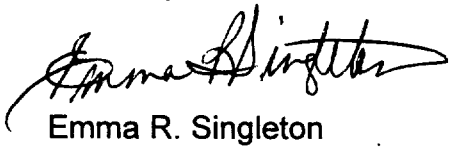
We may take further action if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as monitoring records, revised HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct the remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations, and the cGMP-Regulations for Human Food. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,



Emma R. Singleton
Director, Florida District